SOMANETICS

Section 5 — 510(k) Summary

Date of Submission: ..... August 12, 2008

Device Trade Name: ..... INVOS 5100C Cerebral/Somatic Oximeter System

Device Common Name: ..... Oximeter, Cerebral/Somatic

Device Classification Name: ..... Oximeter, Tissue Saturation (21 CFR 870.2700, Product Code MUD)

Submitted by: .....
Somanetics Corporation
1653 East Maple Road
Troy, MI 48083
Phone: 248-689-3050
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Contact Person: .....
Ronald A. Widman
Vice President, Medical Affairs
248-526-5865
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Predicate Device: ..... Somanetics INVOS 5100C Cerebral/Somatic Oximeter System, K080769

Device Description: ..... The INVOS 5100C is a 2 wavelength, diffuse reflectance spectroscopy system employing near infrared light to estimate the percentage of hemoglobin saturated with oxygen in tissue underneath the sensor. An adhesive sensor containing a light source and 2 photodiodes is applied to the skin over the tissue of interest and the returning light is analyzed for oxyhemoglobin and deoxyhemoglobin light absorption. Absorption signals from the photodiode closer to the light source are subtracted from those from the farther photodiode where the returning photons penetrate more deeply in the tissue. This suppresses absorption events originating in the outer layers of tissue that are common to both photodiodes, including the effects of skin pigmentation and subcutaneous tissues. This method of "spatial resolution" also allows estimation of scattering to improve measurement accuracy.

Accessories	SAFB-SM	Small Adult SomaSensor (>40 kg)
	SPFB	Pediatric SomaSensor (<40 kg)
	IS-C	Infant/Neonatal Cerebral OxyAlert NIRSensor (<40 kg)
	IS-S	Infant/Neonatal Somatic OxyAlert NIRSensor (<40 kg)
	RSC-1	Reusable Sensor Cable Channel 1
	RSC-2	Reusable Sensor Cable Channel 2
	RSC-3	Reusable Sensor Cable Channel 3
	RSC-4	Reusable Sensor Cable Channel 4
	5100C-W	One-year Extension of Warranty
	5100C-M	5100C System Operations Manual
	5100-FTD	Field Test Device
	5100C-RS	Portable Mobile Stand
	5100C-SA	Swivel Arm
	5100C-GCX	Mounting Plate
	5100C-TC	Travel Case
	5100C-USB	USB Flash Drive
	312170	Computer Connection Serial Cable
	VL1	Philips VueLink Adaptor Cable

Indications for Use:..... The noninvasive INVOS 5100C is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use in individuals greater than 2.5 kg at risk for reduced-flow or no-flow ischemic states. It is also intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor in any individual. The clinical value of trend data has not been demonstrated in disease states. The INVOS System should not be used as the sole basis for diagnosis or therapy.

Technological Characteristics:..... Technological characteristics of the device, including design, material, chemical composition and energy source are identical to the INVOS 5100C predicate device.

Performance Data: ..... Extensive literature references and clinical studies are submitted demonstrating the substantial equivalence of the device for its stated indication.

Conclusion Drawn from the Testing:.....The conclusion drawn is that the revised indications for use and labeling are substantially equivalent to the predicate device and do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Somanetics Corporation
% Mr. Ronald A. Widman
VP of Medical Affairs
1653 East Maple Road
Troy, Michigan 48083-4208

APR - 3 2009

Re: K082327
Trade/Device Name: Somanetics INVOS® 5100C System and Accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: MUD
Dated: February 16, 2009
Received: February 17, 2009

Dear Mr. Widman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

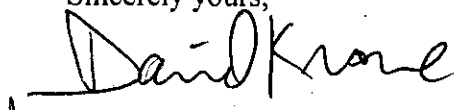
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 **Indications for Use**

510(k) Number (if known) K082327

Device Name: Somanetics INVOS® 5100C System and Accessories

Indications For Use:

The noninvasive INVOS 5100C is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use in individuals greater than 2.5 kg at risk for reduced-flow or no-flow ischemic states.

It is also intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor in any individual. The clinical value of trend data has not been demonstrated in disease states. The INVOS System should not be used as the sole basis for diagnosis or therapy.

Prescription Use__X___ OR Over-The-Counter Use_____
(Part 21 CFR 801 subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082327